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10/685,266

10/14/2003

Yoshiyuki Tatsumi

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06/14/2006

RONALD I. EISENSTEIN
NIXON PEABODY LLP
100 SUMMER STREET
BOSTON, MA 02110

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/685,266 | Applicant(s) TATSUMI ET AL. | |
| | Examiner Dr. Kailash C. Srivastava | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 18-20 is/are pending in the application.
 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 18-20 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/031,929.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 10/14/03&11.22.04.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response filed 06 April 2006 to Election requirement in Office Action mailed 10 March 2006 is acknowledged and entered.
2. For the record, Examiner re-iterates that the correct Serial Number of your Application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/685,266; not Divisional of 10/031,929 as recited in Information Disclosure Statement filed 14 October 2003. Please ensure that the correct U.S. Serial Number (i.e., 10/685,266) for this application is cited in all future correspondence with this Office.
3. Also for the record, the Examiner re-iterates that your application under prosecution at the USPTO is assigned to Dr. Kailash C. Srivastava in Art Unit 1655 and not in 1651 as indicated in the Information Disclosure Statements filed 14 October 2003 and 22 November 2004 respectively. To aid in correlating any papers for this application (i.e., USSN 10/685,266), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

Claims Status

4. Claims 1 and 18-20 are pending.

Restriction/Election

5. Applicants' election without traverse of Group II, Claims 18-20 filed 06 April 2006 to Election requirement in Office Action mailed 10 March 2006 is acknowledged and entered. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claim 1 is withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP §821.03. Examiner suggests that to expedite prosecution, the non-elected claim 1 cited *supra* be canceled in response to this Office action.

6. Claims 18-20 are examined on merits.

Priority

7. Applicants' claim for foreign priority under 35 U.S.C. §119 (a-d) to PCT/JP00/04617 filed 11 July 2000 and under 35 U.S.C. §120 to U.S. Non-Provisional application 10/031, 929 filed 25 January 2002 that has since been abandoned is acknowledged.

Information Disclosure Statement

8. Applicants' Information Disclosure Statements (i.e., IDSs) filed J14 October 2003 and 22 November 2004 respectively have been made of record and considered.

Objection To Specification

9. The specification is objected to because the priority data filed at Page 1 of the amended specification in Applicants' Preliminary amendment dated 14 October 2003 is incorrect. Applicants should appropriately claim this priority as follows:

"This application is a divisional under 35 U.S.C. §120 to U.S. Non-Provisional application 10/031, 929 filed 25 January 2002 that has since been abandoned and said non-provisional U.S. Application was a 371 of PCT/JP00/04617 filed 1 July 2000, which claimed priority to Japan application Serial No.11/214369 filed 28 July 1999."

OBJECTION TO TITLE

10. The title of the invention is not descriptive. A new title is required that clearly indicates the invention to which the claims are directed, which is a method to treat onychomycosis in an individual by administering an antifungal agent. Appropriate correction is required.

Objection To Claims

11. Claim 18 is objected to because of following reasons:

- Claim 18 is objected because of the phrase, "treating subject having onychomycosis comprising administering an effective amount of an antifungal compound having a group represented". This phrase is grammatically improper. Appropriate correction stating said claim in clear and succinct language is required. Appropriate correction is required.

All other claims depend directly or indirectly from the objected claim 18, and are, therefore, also objected for the reasons set forth above.

Double Patenting

12. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Long*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);

In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR §1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

13. Claims 18-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-12 of U.S. Patent No. 5,620,994. Although, conflicting claims are not identical, they are not patentably distinct from each other because claims 9-12 of referenced patent are drawn to a fungicidal composition comprising essentially the same composition as claimed in the cited claims of instant application. The only difference between Claims 18 and 19 of the instant application and prior patent is that in the instant application, the formula II of Claim 19 is claimed in a more generic structure of the antifungal agent as presented in Claim 18. The formula presented in instantly claimed Claim 19 is exactly the same as that in Claim of above-cited patent and Claims 9-12 of said patent claim a process to treat mycosis which again is a generic terminology for "onychomycosis" via administering the compound of formula in Claim 1 of above-referred patent.

14. Claims 18-20 directed to the same invention as that of claims 9-12 of commonly assigned U.S. Patent 5,620,994. The issue of priority under 35 U.S.C. §102(g) and possibly 35 U.S.C. §102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. §§102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

15. Claims 18-20 directed to an invention not patentably distinct from claims 9-12 of commonly assigned U.S. Patent 5,620,994. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent 5,620,994, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. §103(a) if the commonly assigned case qualifies as prior art

under 35 U.S.C. §§102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. §103(c) and 37 C.F.R. §1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. §103(a) based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g), or 35 U.S.C. §102(e) for applications pending on or after December 10, 2004.

Claim Rejections – 35 U.S.C. § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 18-20 are rejected under 35 U.S.C. §102(b) as anticipated by Naito et al. (U.S. Patent 5, 620, 994 or 5,716,969).

Naito et al. teach a fungicidal composition comprising the same compounds, having the same structure (See U.S. Patent 5, 620, 994 Column 17, Line 30 to Column 18, Line19; Column 18, Lines 21-36) as compounds of formula I and II of the instantly claimed invention. Essentially, compound recited as having a group represented by the formula I in instantly claimed claim 18 is a part of formula II compound (Column 12, Lines 1-10 and Claim 1). Even though the antifungal/fungicidal composition taught in the Examiner-cited prior art do not refer to, "therapeutic agent for onychomycosis", to artisan of ordinary skill the claims remain anticipated by the examiner cited prior art because the functional intended use of a composition does not materially change a composition and is accordingly, not given any patentable weight.

Therefore, the reference deems to anticipate claims 18-20.


Conclusion

18. For aforementioned reasons, no Claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1655
(571) 272-0923

June 11, 2006



RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200